COMMENTARY

Linking Research and Policy to Ensure Children's Environmental Health

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The U.S. Environmental Protection Agency (U.S. EPA) has made protecting children's environmental health its highest priority. Data on how and when children may be at risk are vital for accomplishing this goal. Recent examples of the link between research and policy include U.S. EPA actions to carry out the recommendations of the National Academy of Sciences on pesticides in children's food, reduce and prevent childhood lead poisoning, and revise national ambient air quality standards for ozone and particulate matter. Today, the Food Quality Protection Act (FQPA), which makes protecting children from pesticide residues in food a national priority, is contributing to the growing need for data for decision making. Further impetus comes from provisions in the FQPA and 1996 Safe Drinking Water Act Amendments for establishing a screening and testing program for potential risks from endocrine disruptors. Another factor is the analysis that will be required under President William J. Clinton's executive order directing all federal agencies, for the first time, to reduce environmental health and safety risks to children. Success of the U.S. international commitment to protect children is directly tied to the strength and availability of environmental data. To meet such challenges, the U.S. EPA is revising key science policies, expanding research opportunities, and adding to the public's right-to-know tools. In this dynamic climate, there are growing opportunities for the research community to play a greater role in helping ensure the well-being of children living today and in generations to come. — *Environ Health Perspect* 106(Suppl 3): 857–862 (1998). *http://ehpnet1.niehs.nih.gov/docs/1998/Suppl-3/857-862goldman/abstract.html*

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Introduction

The vision for children's environmental health must be a broad one. At the U.S. Environmental Protection Agency (U.S. EPA), the vision that shapes research priorities and policy directions is of a world in which children live in safe homes and communities. It is a world in which environmental resources that enabled present generations to better their lives will be available for future generations. At its core is a sustainable approach to environmental protection—one that recognizes that environmental safeguards and economic development should go hand in hand.

In this view of the future, all stakeholders work together to advance environmental stewardship, forming voluntary partnerships to achieve advances none could accomplish alone. Individuals and institutions develop and share data to strengthen risk assessment and link data to policymaking. Research, regulatory action, and collaboration seek to safeguard children by reducing or preventing exposure to toxic hazards.

Children: The U.S. EPA's Highest Priority

Although great strides have been made in cleaning up the air, water, and land since the first Earth Day in 1970, much remains to be done to bring about a world in which children live in safe homes and communities. A growing body of scientific knowledge shows that children may be disproportionately vulnerable to certain environmental hazards, prompting the need for more data for assessing potential risks.

Responding to such concerns, on 21 April 1997, President William J. Clinton signed Executive Order 13045 to reduce environmental health and safety risks to children (*1*). This executive order requires federal agencies, for the first time, to assign high priority to dealing with these risks, coordinate research priorities on children's health, and ensure that standards take special risks to children into account.

The Clinton administration has made protecting children from environmental hazards the U.S. EPA's highest priority. In 1996 U.S. EPA Administrator Carol Browner issued a national assessment of environmental health threats to children with the establishment of a comprehensive National Agenda to Protect Children's Health from Environmental Threats (*2*). As part of the new national agenda, the agency committed to the following:

- Ensuring, as a matter of national policy, that new public health and environmental standards protect children, and reviewing the most significant existing standards as new data on children's potential health risks emerge. This commitment includes reexamining five of the most significant current standards on an expedited basis.
- Using the best science in measures to protect children. The U.S. EPA will identify and expand research on children's unique susceptibility and exposure to environmental pollutants to inform the standard-setting process.
- Undertaking comprehensive approaches to safeguard children's health—moving beyond the chemical-by-chemical approaches of the past to better reflect cumulative and simultaneous exposures.
- Expanding right-to-know education about children's environmental health risks. The aim is to give families better consumer information about children's risks; to inform parents, teachers, and community leaders how to identify and respond to them; and to educate health professionals to identify, prevent, and reduce toxic threats to children.

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Abbreviations used: CDC, Centers for Disease Control and Prevention; CSFII, Continuing Survey of Food Intakes by Individuals; FQPA, Food Quality Protection Act; NAS, National Academy of Sciences; NHANES, National Health and Nutrition Examination Survey; NIEHS, National Institute of Environmental Health Sciences; PM, particulate matter (number in subscript indicates aerodynamic diameter); TSCA, Toxic Substances Control Act; USDA, U.S. Department of Agriculture; U.S. EPA, U.S. Environmental Protection Agency; U.S. FDA, U.S. Food and Drug Administration; U.S. HUD, U.S. Department of Housing and Urban Development.

The U.S. EPA's national agenda (*2*) built on a series of actions, including Browner's October 1995 directive that all agency programs explicitly evaluate potential hazards to children in their risk assessments (*3*). Another action was Executive Order 12898, which was signed by President Clinton in 1994 and amended in 1995, establishing a new commitment that the federal government address environmental justice concerns in its actions (*4,5*). The agency also created an Office of Children's Health Protection to coordinate agencywide efforts to safeguard children.

The U.S. priority attention for children's environmental health has become international in scope. In May 1997, U.S. EPA leadership was instrumental in persuading environment ministers meeting in advance of the Denver [Colorado] Summit of the Eight (the G-7 countries and Russia) to adopt a declaration aimed at protecting children worldwide from environmental health hazards (*6*). (The G-7 is comprised of the world's seven richest democracies. They are: Britian, Canada, France, Italy, Japan, Germany, and the United States.) This declaration was subsequently endorsed by the June 1997 G-8 summit in Denver. Components of the joint children's health protection plan recommended to summit leaders included setting national environmental protection standards and conducting risk assessments that protect children more explicitly; providing clean safe drinking water; improving air quality; reducing childhood lead poisoning; and increasing research on endocrine-disrupting chemicals. Summit leaders for the first time endorsed measures to safeguard children's health.

New Legislation

At the U.S. EPA, the need for more complete and realistic data on children's environmental health is emerging from implementation of the Food Quality Protection Act (FQPA) of 1996 (*7*). This statute substantially strengthens the U.S. EPA's ability to protect children from exposures to pesticides.

One way it does so is by setting a strong course for screening and testing to generate the information needed to deal with possible risks from endocrine-disrupting chemicals. The FQPA mandates that the U.S. EPA develop and carry out a comprehensive screening and testing program for all pesticides—especially for estrogenic effects—and authorizes screening and testing for other effects.

In addition, the 1996 Safe Drinking Water Act Amendments authorize the U.S. EPA to include in its endocrine screening and testing program not only pesticides but any chemical found in drinking water sources to which substantial numbers of people may be exposed (*8*). These are the first statutes since enactment of the 1976 Toxic Substances Control Act (TSCA) that authorize the U.S. EPA to require chemical testing (*9*).

The statutory timetable calls for creation of a screening and testing program by August 1998; implementation of the screening and testing program by August 1999, including peer review and consultation with the National Academy of Sciences (NAS); and submission of a report to Congress by August 2000.

To help develop a consensus-based approach to the scientific issues involved, the agency established the Endocrine Disruptor Screening and Testing Advisory Committee. Comprising the federal advisory committee are approximately 45 members representing industry; environmental, public health, and environmental justice groups; labor organizations; academia; and federal and state government. Not only the U.S. EPA but also the National Institute of Environmental Health Sciences (NIEHS), the Department of Interior, the U.S. Department of Agriculture (USDA), the U.S. Food and Drug Administration (U.S. FDA), and the U.S. Centers for Disease Control and Prevention (CDC) participate in this activity. All will play key roles in the research, testing, and regulatory decisions to protect health and the environment when it comes to endocrine disrupting chemicals.

The FQPA requires an explicit determination that pesticide tolerances—the legal limits on pesticide residues on certain food crops—are safe for children or they will not be approved. Under the statute, the U.S. EPA must consider prenatal and postnatal effects. The agency also must weigh aggregate exposure from multiple routes and cumulative risks resulting from simultaneous exposure to multiple chemicals with a similar mechanism of action. The new approach to setting tolerances for pesticides will be more complete and therefore more realistic.

To use such comprehensive provisions to protect children effectively, more and better data will be needed in a range of areas. These include residential exposure, *in utero* exposure in comparison to exposure later in life, and developmental end points when low-level exposure is of particular concern. There now are statutory provisions that direct regulators to consider a comprehensive picture of potential health risks, particularly for children, in setting conditions for pesticide use. There must be more and better data with which to use such provisions effectively.

What is particularly worrisome is that most analyses of environmental health risks are not drawn from real-world experience; rather, they are based on extrapolation from animal studies. Although inroads have been made in identifying and evaluating environmental risks to children, there is a long way to go.

The Broader Context: Research on Children in the United States

The issue of investing in research to improve the lives of children is one that, of course, goes well beyond environmental health and the regulatory responsibilities of the U.S. EPA. It is important to understand this context when addressing the specific issue of research relevant to environmental health.

Children will have a better chance of leading healthy productive lives if scientists in the public and private sectors focus more extensively on research issues that affect them, including environmental ones. This was a central conclusion of a multiagency effort conducted on behalf of the National Science and Technology Council to evaluate the federal research agenda for children. The project was done on behalf of the council's committees on fundamental science and health, safety, and food.

The study resulted in a report entitled *Investing in Our Future—A National Research Initiative for America's Children for the 21st Century* (*10*). The study had a number of relevant findings.

- Unlike other areas of research, almost all research for children—more than 90%—is funded by the federal government. This research commitment involves dozens of agencies and is a multidisciplinary activity.
- Of the $500 billion spent by government at all levels to educate and address children and adolescents directly, less than 0.4 of 1% is spent for research to leverage and guide these efforts.
- Less than 3% of the overall federal domestic research budget is spent for research directly related to children.

Clearly there is room for improvement. Childhood is the optimal time to intervene for chronic diseases and other outcomes

later in life. The science to assess growth and development is growing rapidly, providing opportunities for linkages. Policymakers in all areas related to children must be informed by the best science.

Linkage between Research and Policy in Environmental Regulation

What are the implications in the arena of environmental policy? Clearly there can be a powerful link between research and policy. The time is ripe for new research focused on children's health and environmental risk. Such research must be multidisciplinary in nature and coordinated across the relevant federal agencies. The following three examples illustrate this connection. The first example involves pesticides; the second, lead; and the third, air pollution.

Pesticides Residues in Food

In 1993 the NAS completed a landmark study on environmental risks to children entitled *Pesticides in the Diets of Infants and Children* (*11*). By evaluating existing information on pesticides in the diets of infants and children, the NAS report concluded that children face unique vulnerability to environmental hazards compared to adults and need commensurate safeguards. For example, children consume more of some food and fluids relative to their body size than adults do, and thus can encounter a comparatively higher level of exposure to pesticides. The NAS report looked at the issue of infant consumption of certain food commodities. In its data comparison, the report found that consumption by infants and children is above the U.S. adult average for apple juice, milk (nonfat solids), apples, bananas, milk sugar (lactose), peaches, pears, carrots, oats, soybean oil, wheat flour, milk-fat solids, and lean beef.

At the same time, children's systems are still developing, potentially increasing their susceptibility to toxic influences. Their unique behavior exposes them more to certain pollutants and related health risks. This behavior includes crawling on the ground, playing outside, and (especially for infants and toddlers) having extensive hand-to-mouth activity.

Based on the combination of factors, the NAS report recommended that government do more to address the unique risks posed to children. The agency began implementing many of the NAS recommendations immediately. The FQPA gives statutory direction to the new national commitment to protecting children from dietary exposure to pesticides.

Therefore, the new pesticide law will provide incentives for testing and research on the potential for risk from the 620 active ingredient pesticides currently registered. These are formulated into the approximately 20,000 pesticide products that are on the market today.

To protect infants and children under the FQPA, the agency is authorized to consider adding an extra safety factor in interpreting animal toxicity data when they are incomplete or unreliable in reflecting pre- or postnatal toxicity or when they indicate effects of concern. The agency now will account for cumulative risk to pesticides that function according to a common mode of action and to aggregate exposures from all known sources (including agricultural, lawn and garden, indoor, and pet uses) and pathways (including dietary, dermal, inhalation, and hand- or object-to-mouth ingestion). All of this inevitably will result in the generation of new scientific data on exposures and risks.

In the case of pesticide residues in food and potential health risks to children, rigorous evaluation of available data and research led to policy recommendations that in turn resulted in national policy. Today, the need for involvement of the scientific community in generating additional data is greater than ever. There are significant opportunities for contributing insight, expertise, and research in a number of areas.

Research. The U.S. EPA's Office of Research and Development is expanding its program on children's environmental health issues, with research aimed at developing a better understanding of how and why children's exposures and responses to pollutants are different from those of adults. The work will pay specific attention to differences in exposure; to physiology, biology, and mechanisms of action; and to improved ways to perform quantitative risk assessment. The Office of Research and Development grants program, Science to Achieve Results, has funded several projects to explore children's exposure to pesticides and in 1998 will announce additional grant opportunities involving children's issues. Information and grant program announcements appear on the Office of Research and Development Internet web page for the National Center for Environmental Research and Quality Assurance (*12*).

Other federal agencies are playing critical roles. The NIEHS has expanded research efforts into developmental and reproductive toxicity. The CDC has monitored pesticide levels previously, for example in the National Health and Nutrition Examination Survey (NHANES) III (*13*). The next survey, NHANES IV, in addition to implementing the use of urinary biomarkers for pesticide exposure, will survey participants' use of pesticides in the residential environment. The USDA Agricultural Marketing Service Pesticide Data Program has increased the monitoring of pesticide residues in foods eaten by children. The USDA Agricultural Research Service collected and is releasing current food consumption data from one of its periodic food consumption surveys, the 1994 to 1996 Continuing Survey of Food Intakes by Individuals (CSFII) (*14,15*). Further, the USDA now has a survey underway that is collecting additional food intake data on infants and children. This latter survey will supplement the 1994 to 1996 CSFII and uses the same methodology so that the results can be merged, thereby providing a larger pool of intake data for infants and children to aid in better understanding dietary intake patterns for young children.

Policy. The U.S. EPA is developing new science policies on identifying common mechanisms of action, aggregating exposure from different sources and pathways, and testing for prenatal and postnatal risks (*16*).

Right-to-Know and Consumer Information. The U.S. EPA is moving to satisfy the FQPA requirement to develop information for grocery stores on potential health risks from pesticide residues in food (*7*). The agency is also committed to a comprehensive approach for improving consumer information on pesticide products.

Prevention of Childhood Lead Exposure

Blood lead levels previously considered safe are now known to be associated with adverse health effects in children. Since 1970, the level of concern for blood lead has been revised downward, from 60 to 10 μg/dl. Research with more sensitive measures and better study designs demonstrated that the level of concern for childhood lead poisoning should be lowered. This research was largely supported by the federal government, especially the NIEHS, the CDC, and the U.S. EPA.

Over this same time span from 1970 to the present, a number of federal policy actions were taken to reduce exposures to lead. These actions include several laws and

standards: the 1971 Lead-Based Paint Poisoning Prevention Act (*17*); the U.S. EPA phaseout of lead in gasoline starting in 1973 (*18*) with completion at the end of 1995 (*19*); the U.S. EPA ban on use of lead in plumbing, fixtures, fittings, and solder (*20*); the U.S. Consumer Product Safety Commission 1978 standard limiting the allowable amount of lead in paint (*21*); the reduction and elimination of the lead in solder for food cans in the United States, with the final U.S. FDA rule effective in December 1995 (*22*); the Residential Lead-Based Paint Hazard Reduction Act of 1992 (*23*) (generally referred to as Title X), which mandated additional actions by the U.S. EPA, the U.S. Department of Housing and Urban Development (HUD), and other federal agencies. Title X requirements involving the U.S. EPA include new efforts on education; training and certification/standards for abatement activities; real estate notification (giving the public the right to know about the presence of lead in a home before buying or renting it); and development of lead-contaminated soil and dust standards (*23*).

Much of this work has been accomplished, but there is still much to do. The U.S. EPA must develop lead-contaminated soil and dust standards. States need to adopt abatement programs. Important strides have been made through education, but the sources of lead hazards must be removed from children's environments.

Measures to prevent and reduce childhood lead poisoning have paid great dividends (Figure 1). According to the most recent report from the CDC, NHANES III, data show the rate of lead poisoning has been halved since the beginning of this decade and continues the downward trend observed since the late 1970s (*24*). At that time, the average blood lead level in children 1 to 5 years of age was 15 µg/dl. Average blood lead levels today are 2.7 µg/dl. In the late 1970s almost 88% of children 1 to 5 years of age had elevated blood lead levels, compared to approximately 4.4% of children today.

Although tremendous progress has been made, the most recent data from the CDC also show that there are still as many as 900,000 children under 6 years of age with blood lead levels at or above 10 µg/dl. The challenge today is to stay the course with prevention of childhood lead poisoning to address the ultimate goal—eradication of this preventable disease. The new data call for fine-tuning to ensure that the U.S. EPA, the CDC, the U.S. HUD, the states, and others are targeting efforts in the most effective way possible. In particular, there is a need to focus efforts on the remaining pockets of lead poisoning in low income, minority, and inner-city areas.

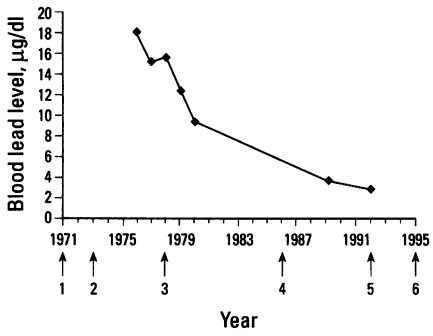

Figure 1. Chronological trend in blood lead levels for U.S. children 1 to 5 years of age and regulatory actions taken to reduce lead exposure to children, 1971 to 1995. Federal actions: *1*) 1971, Lead-Based Paint Poisoning Prevention Act (*17*); *2*) 1973, U.S. EPA begins phaseout of lead in gasoline (*18*); *3*) 1978, U.S. Consumer Product Safety Commission bans sale and distribution of lead-based paint (*21*); *4*) 1986, lead in plumbing, fixtures, fittings, and solder banned (*20*); *5*) 1992, Lead Title X to abate lead hazards in housing (*23*); *6*) 1995, U.S. EPA completes phaseout of leaded gasoline (*19*).

Air Pollution Standards

Responding to the growing body of research on air pollution's potential harm to human health, in late 1996 the U.S. EPA proposed to strengthen the national ambient air quality standards for particulate matter and ozone—better known as soot and smog (*25,26*).

The Clean Air Act directs the U.S. EPA to review the public health standards for major air pollutants at least every 5 years to ensure that they reflect the best current science (*27*). It lays out a specific procedure to obtain the best available current science and, if needed, to revise the standards. The U.S. EPA missed the statutory deadline for reviewing the standards, and a number of organizations, including the American Academy of Pediatrics' Committee on Environmental Health, urged the U.S. EPA to revisit the standards promptly and take risks for children into account (*28*).

In the review process that led to the air pollution standard revisions, a broad range of peer-reviewed scientific evidence was examined. The U.S. EPA began by conducting a wide-ranging literature search, covering all aspects of ozone and particulate pollution. The agency then selected studies relevant to human health effects for review. During a 3-year period, the U.S. EPA and two independent scientific review panels identified 185 key epidemiologic studies on the human health effects of ozone pollution (*29*) and 86 studies on the links between human health and particulate matter pollution (*30*). Controlled clinical, epidemiologic, and toxicologic studies were included in this examination. Study after study indicated that the air standards were not adequately protecting public health and that they should be strengthened.

To combat smog, the U.S. EPA changed the ozone standard from 0.12 ppm of ozone measured over 1 hr to a standard of 0.08 ppm measured over 8 hr (*31*). The U.S. EPA's Science Advisory Board and others advised that there is a strong scientific basis for changing from a 1-hr standard to an 8-hr standard. The 0.12 ppm 1-hr standard is roughly equivalent to 0.09 ppm when measured over 8 hr. In terms of its overall effect, the U.S. EPA changed the concentration from 0.09 to 0.08 ppm to provide the needed measure of public health protection called for by the science.

Children who are active outdoors are at greatest risk from ozone pollution and consequent diminishment of lung function. The U.S. EPA has been ridiculed by some for its concern over these lung function changes, many of which are physiologically reversible. However, although the physiologic changes may be reversible, there are other consequences that can be long term and difficult to monetize in a cost–benefit analysis. An asthmatic child who, because of air pollution levels, cannot exercise midday and who cannot fully engage in age-appropriate physical activities with peers could suffer physical and developmental effects of lifetime duration. What is it worth to a child to be able to play outside with friends? We do not know how to answer this question, but these effects are nonetheless of concern for children's health.

To deal with soot, the U.S. EPA maintained standards for the current indicator for particulate matter, which included the larger, coarse particles ≤ 10 µm in diameter (PM_{10}), and set new standards for smaller particles—those ≤2.5 µm in diameter ($PM_{2.5}$) (*32*). A number of avenues of research point to the smaller particles as most damaging to human health. The standards for $PM_{2.5}$ are 15 µg/m^3 annual average and 65 µg/m^3 on a 24-hr basis. The revisions are set at levels

to protect public health with an adequate margin of safety.

Health benefits from carrying out these standards will add substantially to benefits contributed by implementation of other Clean Air Act programs, such as controls for acid rain.

Once again, in this air pollution example, there is a dynamic link between research and policy—a link that promises to enable more Americans to enjoy cleaner healthier air.

A Challenge for the Future: Toxic Substances

How is the U.S. EPA addressing other chemicals in commerce in its policymaking? Are the data sufficient for weighing potential risks? Here, again, a great deal of work needs to be done. TSCA (*9*), enacted in 1976, is in need of careful reassessment and change to bring about improved protection of human health and the environment.

Approximately 70,000 industrial chemicals are commercially produced or imported into the United States and are on the TSCA inventory. Approximately 15,000 of these industrial chemicals are not polymers and are produced or imported in amounts >10,000 lb/year. These chemicals are of concern and come within the broad focus of the agency's chemical testing and assessment programs under TSCA. Approximately 3000 of these 15,000 chemicals are high-production-volume chemicals—those produced or imported in amounts >1 million lb/year. These chemicals are the primary focus of the TSCA chemical testing and assessment efforts (*33*).

Since 1976 the U.S. EPA has required testing on approximately 500 existing chemicals. In comparison, about 2000 new chemicals are brought to the agency for review every year, typically without accompanying health and safety data. The U.S. National Toxicology Program has only limited capacity to test toxic chemicals.

Clearly, the capacity to produce new chemicals has outstripped the capacity to test chemicals. Section 2 of TSCA states that "adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and development of such data be the responsibility of those who manufacture and those who process such chemicals and mixtures" (*9*). However, TSCA does not give the U.S. EPA effective or efficient tools with which to require the chemical testing needed for assessment and decision making.

TSCA test rules frequently bog down in cumbersome statutory procedural requirements that continue to frustrate one of the most important mandates of the act—to test chemicals to obtain adequate health and safety data with which to support scientifically sound risk assessment and management and to place the burden for that testing on chemical producers, importers, and processors.

To increase testing and avoid, whenever possible, the regulatory complexities involved with issuing formal TSCA test rules, the agency has been drawing much more heavily in the last several years on alternative testing mechanisms such as enforceable consent agreements and voluntary testing programs.

Even with increased use of these alternative mechanisms, which have resulted in more testing, the overall level of chemical testing is still disappointing. At the core of the problem is the inefficient rule-making tools that TSCA gives the U.S. EPA for carrying out the clear chemical-testing mandate embodied in this 20-year-old law.

Conclusion

Three conclusions can be drawn from this review.

Policymakers need the results of more research and testing to understand risks for children. There is an enormous amount of work to be done not only on new chemicals but on existing ones as well. Moreover, the parameters for research and testing need to be broader, to include, for example, prenatal health effects.

The government needs to make better use of available information to ensure that health and safety policies protect children. This means that scientists and child health experts need to participate in the policymaking process and make use of the significant opportunities for multidisciplinary cooperation and collaboration.

Information must be made readily and easily available to communities at all levels in user-friendly ways to ensure that citizens and consumers have the information they need to safeguard their children. This means finding the most effective avenue (for example, the federal Toxic Release Inventory of chemicals released to the air, water, and land (*34*); consumer labels; medical providers; the Internet; and local information sources such as schools and libraries) to convey sound scientific information about potential health risks.

There is a clear need for the data essential for making effective policy decisions. With greater cooperation between and among the public and private research communities, much can be accomplished to safeguard children's environmental health for today and tomorrow.

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